

Nelson, Bettie L

From: Nelson, Bettie L
Sent: Monday, October 22, 2001 10:36 AM
To: Roethig, Hans
Subject: FW: Update on the programming progress

Hans,

Below is correspondence with Rachid of Covance regarding the status of programming and the generation of tables and listings. Data from the CRFs and Questionnaires have been programmed and are currently undergoing QC processing. Expectations are that this will be completed by mid-November. With regards to the biomarker data, their plans are to submit all biomarker data to QC processing by the end of January when all of the data for the biomarkers are received.

The information for the tables and listings pertaining to the biomarkers is contained in one program and therefore reviewing the data for a single biomarker would necessitate multiple QCs as the data would undergo QC processing whenever a new biomarker is added. Covance will be able to provide portions of the analyses that maybe updated as we go farther along.

If you need additional information or if the timelines as indicated here are not in line with what we need, please let me know.

With best regards,

Bettie

-----Original Message-----

From: Rachid Chaouki [SMTP:rachid.chaouki@Covance.Com] <<mailto:SMTP:rachid.chaouki@Covance.Com>>
Sent: Friday, October 19, 2001 3:42 PM
To: Bettie.L.Nelson@pmusa.com
Subject: Fwd: Update on the programming progress

Dear Bettie,

Please note that Section 16.1 that I have listed in the previous email has not been done yet.

My apologies.

Thank you

Rachid Chaouki, MS
Biostatistician
Data Services and Biostatistics
rachid.chaouki@covance.com

Date: Fri, 19 Oct 2001 14:00:07 -0500
From: "Rachid Chaouki" <rachid.chaouki@covance.com <<mailto:rachid.chaouki@covance.com>>>
To: <Bettie.L.Nelson@pmusa.com <<mailto:Bettie.L.Nelson@pmusa.com>>>
Subject: Update on the programming progress

Dear Bettie,

Here is an update in regards to where we are. Please see the RAP's Table of Contents for reference. All the tables and

listings (based on data from CRFs/Questionnaire) below have gone through the programming phase since we have all the data available for them . They are currently going through the quality control Phase. The programming regarding the biomarkers is ongoing and expected to be totally finished and submitted for quality control around the end of January. All the repeated measures portion of the statistical analyses (programming) are expected to be finished by the end of next month. We do expect to send you some of the tables and listings by mid November (including some biomarkers data). Nonlinear analyses are expected to begin on December. Please realize that we expect to receive all the biomarker data no earlier than January 18. However we are moving with the programming as the data are obtained. Please let me know if you have any other questions.

Section 14.3
Table 14.3.1-2
Table 14.3.2-2

Section 14.6 (all)
Section 14.7 (all)

appendix
Section 16.1
Listing 16.3-24 to Listing 16.3-38 section 16.3 (all)

Thank you

Rachid Chaouki, MS
Biostatistician
Data Services and Biostatistics
rachid.chaouki@covance.com

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Nelson, Bettie L

From: Nelson, Bettie L
Sent: Wednesday, October 17, 2001 3:06 PM
To: Roethig, Hans
Subject: BIOMARKERS MEETING

Hans,

We didn't complete the discussion about the Biomarkers meeting. I had inquired earlier about the meeting and then events happened and I did not get back to it. Should I make plans to attend?

With best regards,

Bettie